



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

March 31, 1999

**MEMORANDUM:**

**Subject:** Efficacy Review and Label Review for "Low Phenolic 256"  
EPA Reg. No. 211-62. Case No. 046785  
DP Barcode: D251677

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**Applicant:** Central Solution, Inc.,  
3130 Brinkerhoff Road  
Kansas, City, KS 66115

**FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Ortho-Phenylphenol.....	8.085
Orthobenzyl-Benzyl-para-Chlorophenol.....	8.650
<u>Inert Ingredient(s)</u> .....	85.265
Total.....	100.000



## BACKGROUND:

The subject product "Low pH Phenolic 256" is registered as a disinfectant for use in hospitals, medical offices, nursing homes, health care institutions, and establishments which are dedicated to controlling the hazards of cross contamination. This product is also registered as a broad spectrum disinfectant against a variety of pathogenic bacteria which are indicated in the last accepted label dated 02-20-98. The product's labeling also contains claims which are reported to be fungicidal, tuberculocidal, virucidal, bactericidal, and germicidal - detergent with effectiveness in the presence of organic soil and hard water. For other additional uses, refer to the accepted label dated 02-20-98.

The current submission is an amendment to add virucidal claims for *Influenza virus type A/2,ATCC VR-544*, Strain Hong Kong and *Vaccinia virus ATCC VR-119*, Strain WR. This amendment also proposes to expand and clarify the product directions for use on surfaces of non-medical, semi-critical and critical medical devices.

Documentation in the form of 510(K) pre-market clearance by the Food and Drug Administration (FDA) is also included with this submission in support a usage for surfaces of non-medical, semi-critical and critical devices.

The present submission contains virucidal efficacy data (MRID #447086-01 & -02) and a proposed label in support of this amendment. All data reports and proposed labeling are reviewed and summarized below.

## RECOMMENDATIONS:

### *EFFICACY SUPPORTED by the SUBMITTED DATA:*

The submitted virucidal efficacy data developed by the EPA Modified Test Method (Subdivision G, Product Performance Guidelines, DIS/TSS-7 Enclosure) are adequate and supportive of the product as a virucide.

Effectiveness was demonstrated against *Influenza Virus Type A/2/Hong Kong (ATCC VR-544)* and *Vaccinia Virus Strain WR (ATCC VR-119)* in the presence of 5% fetal bovine serum and 400 ppm of synthetic hard water at a 1:256 dilution for hard, nonporous inanimate surfaces when thoroughly wetted by the solution and when allowed to remain wet for a 10 minute exposure time.

## LABELING:

The following comments are applicable for the proposed label "Low pH Phenolic 256" pinpunched dated 12-04-98. .

1. No adverse comments for pages #1 through #8.

2. At the bottom of page #9, revise "shoebaths" to read "shoebaths sanitizer". For this use pattern, the highest level of activity the Agency will allow is at the sanitization level. The above comment for page #9 was previously provided in a label review. Refer to the efficacy review dated 10-17-96.
3. No adverse comments for page #10.
4. The comments indicated above for page #9 are also applicable for the bottom of page #11.
5. No adverse comments for pages #12, #13, #14, and #15.
6. On page #16, in the second paragraph, delete the phrase "including most plastics", and list the specific type of plastics on which the product is intended to be used. The use of the phrase "including most plastics" is considered too broad and is unacceptable.
7. No adverse comments on pages #17 and #18.
8. On page #19, at the top of the page, and following the term viruses, add "on hard, inanimate surfaces".